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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,936	03/25/2005	Ayrookaran J. Poulose	GC717-2-US	1489

5100 7590 10/29/2007

GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,936	POULOSE, AYROOKARAN J.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070821*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's petition to revive this application filed on 21 August 2007 was granted in the communication mailed 27 September 2007 and the amended claims provided in the Response accompanying the petition of 21 August 2007 were entered. Since claims 4-8 and 11-14 had been canceled in the Response filed 26 September 2006, claims 1-4 and 15-18 are pending in the application.

Information Disclosure Statement

Applicant's Information Disclosure Statement [IDS] filed on 21 August 2007 is hereby acknowledged and executed copies of the three pages of PTO-Form 1449 submitted with the IDS accompany this communication.

Specification

The disclosure is objected to because of the following informalities: (1) The paragraph beginning at line 14 of page 19 of the specification lacks sequence identifiers for the compared amino acid sequences of the *Bacillus amyloliqefaciens* subtilisin and the *Bacillus lentus* GG36 subtilisin, does not identify the list of numbers as positions for substitution, and fails to identify position 147, which is indicated as a position for substitution in Table 1. (2) The footnote at the bottom of page 30 erroneously states SEQ ID NO:4 where SEQ ID NO:6 is the proper sequence identifier for the amino acid sequence of the *Bacillus lentus* GG35 subtilisin. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope

of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 15-18 remain provisionally rejected for reasons of record on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 18 of copending Application No. 10/498,714. Applicant indicates at page 6 of the Response of 21 August 2007 that a Terminal Disclaimer would be provided upon indication of allowable subject matter but the rejection of record must be maintained unless and until a Terminal Disclaimer is filed. While the conflicting claims are not identical, they are not patentably distinct from each other because functional limitations of the modified proteases recited by the amended claims 1-3 herein, which remain generic proteases, and features of the encoding DNAs, expression vectors, host cells, and cleaning compositions of claims 15-18 herein, fail to distinguish the inherently identical structures of modified proteases, encoding DNA, expression vectors, host cells, and cleaning compositions embraced by the claims 1-8 and 18 of the copending application which describe amino acid substitutions at the subtilisin BPN'-correspondent position 26 in a generic subtilisin. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 3 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

This is essentially the rejection of record because the amended claims 1-3 still describe a generic protease, the wash performance, stability, and/or thermostability of which, must be compared to a native *Bacillus lentus* GG36 subtilisin but the specification fails to exemplify or describe an improved wash performance, or an improved stability, either for a generic subtilisin or for a mature subtilisin BPN', the reference for registering the positions 26 and 218, that has an improved characteristic relative to the native *Bacillus lentus* CG36 subtilisin other than a modified *Bacillus lentus* CG36 subtilisin. Applicant's arguments in the Response of 21 August 2007 have been considered but are not persuasive because the claim amendments provided in the Response are not in accord with these arguments where the specification discloses only an

improved thermal stability, and a correspondingly improved wash performance at elevated temperatures, for a specific set of CG36 subtilisin variants, including the variant modified by an amino acid substitution of either V26T or V26S, as well as a N218S substitution. Thus the rejection of record is sustained.

Claims 2 and 3 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the preparation of modified CG36 subtilisins comprising amino acid substitutions of either V26S or V26T that have improved thermal stability by comparison with an unmodified CG36 subtilisin,

does not reasonably provide enablement for the preparation of modified **generic** subtilisins comprising amino acid substitutions of either valine or threonine at a position corresponding to position 36 in the amino acid sequence of subtilisin BPN' set forth in SEQ ID NO:3 that have improved thermal stability or improved wash performance by comparison with the stability and/or wash performance of the unmodified CG36 subtilisin set forth in SEQ ID NO:6.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This is essentially the rejection of record because the amended claims 2 and 3 still describe a generic protease, the wash performance, stability, and/or thermostability of which, must be improved by comparison with a native *Bacillus lentus* GG36 subtilisin but the specification fails to exemplify or describe an improved wash performance, or an improved stability, either for a generic subtilisin or for a mature subtilisin BPN'. Again, Applicant's arguments in the Response of 21 August 2007 have been fully considered but are not persuasive because the claim amendments provided in the Response are not in accord with the stated arguments where the specification, even if taken in combination with the prior art of record herein, fails to enable the modification of generic subtilisins to improve thermal stability, to improve wash performance, by providing an amino acid substitution of either V26T or V26S in such generic subtilisins, even if combined with an N218S substitution in a generic subtilisin. Claims 2 and 3 contemplate modifications, beyond the V26T or V26S and N218S modifications of claim 1, of generic subtilisins to provide modified, generic, subtilisin having better stability and better wash performance by comparison with the wash performance or thermal stability of a modified *Bacillus lentus* GG36 subtilisin yet the specification does not support introduction of unspecified amino acid alterations in the amino acid sequences of generic subtilisins to provide these improved characteristics in a generic subtilase, compared with the particular modifications in the particular amino acid sequence of SEQ ID NO:6. Thus the rejection of record is sustained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-3 and 15-18 remain rejected for reasons of record under 35 U.S.C. § 102(e) as being anticipated by Estell et al., US 2005/0148159.

This is essentially the rejection of record. Applicant's arguments in the Response of 21 August 2007 have been fully considered but are not persuasive. Applicant suggests that the disclosure of Estell et al. of a change in one characteristic of a subtilisin does not meet the limitations of the claims, even though the modifications disclosed by Estell et al. in a generic subtilisin are the same modifications, and will inherently provide the characteristics required by the claims herein, when introduced as modifications in a *Bacillus lentus* GG36 subtilisin. Estell et al. need not disclose alternative characteristics of a *Bacillus lentus* GG36 subtilisin modified according to the disclosures at paragraphs 0053, 0090, 0127 and 0250, where their disclosure of the modifications inherently confers the characteristics required by claims 1-3 herein. Estell et al. further disclose DNAs that encode the modified subtilisins, expression vectors comprising the DNAs, host cells transformed the expression vectors, and cleaning compositions comprising the modified subtilisins, meeting limitations of claims 15-18 herein. See paragraphs 0049, 0054, 0059, 0067-0071, and 0076-0084. The rejection of record is therefore maintained.

Claims 1-3 and 15-18 remain rejected for reasons of record under 35 U.S.C. § 102(f) because the claimed invention was made by another who was the first inventor of the claimed subject matter.

Applicant does not separately argue the rejection of record of claims herein under 35 U.S.C. § 102(f). As noted above, the priority document of Estell et al., US 2005/0148159 fully discloses the invention described by claims 1-3 and 15-18. The seventeen-page priority document claimed for the present application, US provisional application serial No. 60/350,221 filed 16 January 2002, however fails to disclose the particular protease variants of claim 1 herein, DNAs encoding same, vectors and host cells comprising such DNAs, or compositions comprising these particular protease variants, and also fails to disclose any particular protease variants that satisfy the limitations of claim 2 or 3. Indeed, pages 5, 13, 14, and 16 of the priority document disclose no subtilisin comprising either a V26S or a V26T, or further comprising a stabilizing N218S amino acid substitution, where the positions are numbered according to the amino acid sequence of the mature *Bacillus amyloliquefaciens* subtilisin. Neither does the US provisional application serial No. 60/350,221 provide any Tables provided disclosing a subtilisin

comprising either a V26S or a V26T, or further comprising a stabilizing N218S amino acid substitution. Thus the rejection of record is sustained because the inventive entity of Estell et al., an entity other than the instant Applicant, was clearly the first to invent the claimed subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

/Nashed/
Nashaat T. Nashed, Ph.D.
Primary Examiner, Art Unit 1656

William W. Moore
21 October 2007